k000995

OCT 11 2000

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): Heyer America
1320 Old Chain Bridge Rd.
McLean, VA 22101

Phone: 703-506-0040
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Contact Person: Hans Schmidt

Date of Summary: March 15, 2000

Trade Name: Heyer America® 2000

Classification Name: Anesthesia Gas Machine,21CFR section 868.5160

Predicate Device: K963481 Anodyne CC Heyer America

Device Description Comparison:

The HEYER America® 2000 Anesthesia System is a standalone anesthesia device. The device is a reusable, non-sterile, life-supporting anesthesia machine for prescription use in hospitals, clinics and surgery centers.

The device is software driven. Adequate software testing with respect to the new IEC 601-1-4 has been conducted on the device. The device is electrically operated.

Intended Use: The 2000 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

Executive Summary

The HEYER America® 2000 Anesthesia system is a standalone anesthesia device that is intended to use for the administration of anesthetic treatment on adults and children by professional anesthetists in locations such as hospitals, clinics and surgery centers.

We believe the HEYER America® 2000 Anesthesia system to be substantially equivalent to legally marketed predicate anesthesia system:

Manufacturer	Model	Reference number
HEYER America®	Anodyne cc	K963481

Discussion of Similarities and Differences

In all operating areas the 2000 uses the same software as the Anodyne cc. The devices use the same technology, have many identical components and have the same intended use. The major differences between the 2000 and the legally marketed Anodyne are - in the design of the device's frame and reduction in size, accommodating two vaporizers rather than three. This will allow the device to be more effectively presented to surgery centers and other facilities with smaller operating rooms.

Both major differences will neither effect the safety of the patient nor the safety of the clinician.

Another main point of similarity is - the integrated design of the Patient Module, absorber and ventilator bellows which are identical between the 2000 and the Anodyne cc.

On the following pages there is a summary of the similarities and differences between the device under review and the legally marketed devices for:

- Intended Use
- Specifications
- Materials
- Design
- Method of operation and Technology used

Intended Use

Similarities

The HEYER America® 2000 Anesthesia system has the identical intended use as the legally marketed device HEYER America Anodyne cc.

The HEYER America® 2000 Anesthesia system is a medical device intended to use for anesthesia treatment on human patients by professional anesthetists in locations such as hospitals, clinics and surgery centers.

The HEYER America® 2000 Anesthesia system provides capabilities for metabolic gas supply to the patient, anesthetic gas supply to the patient, ventilating the patient and ventilatory monitoring of the Patient.

The HEYER America® 2000 Anesthesia system is intended to be used on Adults and Children.

Differences

None.

Specifications

Similarities

The HEYER America® 2000 Anesthesia system has similar

- physical features
- pneumatic specifications
- electrical specifications
- ventilator specifications
- rebreathing circuit specifications
- volume monitoring specifications
- oxygen monitoring specifications
- airway pressure monitoring specifications
- display systems
- alarm management specifications

as the legally marketed device,

HEYER America® Anodyne CC

The integrated patient module, absorber and ventilator bellows are physically identical between the 2000 and Anodyne.

The industrial PC, Ventilator Electronic Modules and Power Supply System are identical between the 2000 and Anodyne cc.

The 2000 and Anodyne cc both provide a detachable vaporizer system with a so called " SELECTATEC®" mount. An interlock system provides the use of only one vaporizer at a time.

In oxygen monitoring the legally marketed device uses the identical fuel-cell type oxygen sensors, as does the HEYER America® 2000 Anesthesia system.

The HEYER America® 2000 Anesthesia system provides an optical data interface for connecting to a data manager or network, due to the better immunity of the fiber optics against electromagnetic interference the same as the Anodyne cc.

Differences:

The 2000 has a redesigned frame when compared to the Anodyne cc. Also, the 2000 system has been reduced in size allowing a maximum of two vaporizers rather then three on the Anodyne.

Materials

Similarities

The HEYER America® 2000 Anesthesia system uses similar materials as the legally marketed devices,

HEYER America	Anodyne cc

Especially the materials used for patient gas conditioning and control are identical between the 2000 and Anodyne.

Differences

None

Design

Similarities

The HEYER America® 2000 anesthesia system uses a similar design as the legally marketed device,

HEYER America®	Anodyne CC

due to requirements of the market and some particular standards.

With respect to the sketches attached to this 510 (k) submission, one can see that there is the same basic design, having

- vaporizers mounted at eye level
- a three gas, flowmeter assembly in the middle
- a ventilator and monitoring screen at eye level
- drawers on the right for storage.
- Monitor shelf on top
- Patient module with absorber and ventilator bellows
- Integrated Flow sensor in the Patient Module

Differences

Again the primary difference is the size of the frame has been reduced on the 2000 accommodating up to two vaporizers.

Method of operation / Technology used

Similarities

The HEYER America® 2000 Anesthesia system uses similar methods of operation and technology as the legally marketed device,

HEYER America® Anodyne CC

such as :

- High pressure gas management
- Low pressure gas management
- Flowmetering
- Flowcontrol
- Vaporizer Mounting
- Ventilator modes
- Bellows principle
- Absorber principle
- Rebreathing circuit principle
- Hypoxic guard
- Spirometry measurement
- Pressure measurement
- Oxygen monitoring
- External Data Communication Port

Differences

None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1 2000

Heyer America, Inc.
c/o Mr. Arthur J. Ward
Regulatory & Marketing Services, Inc.
3234 Ella Lane
New Port Richey, FL 34655

Re: K000995
Narkomat 2000 Anesthesia System
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: July 13, 2000
Received: July 17, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000995

Device Name: Heyer America® Narkomat 2000 Anesthesia System

Indications For Use:

The Narkomat 2000 Anesthesia System is a device used to administer to a patient, continuously or intermittently, a general inhalation anesthetic and to maintain a patient's ventilation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000995

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)